STATE OF NEW YORK
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ATTORNEY GENERAL

February 12, 2021

Via Federal eRulemaking Portal
Acting Secretary Norris Cochran
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Comments on Proposed Rule: *Establishment of Safeguards and Program Integrity Requirements for Health and Human Services-Funded Extramural Research Involving Human Fetal Tissue*, 86 Fed. Reg. 2615 (January 13, 2021), 47 RIN 0991-AC15

Dear Acting Secretary Cochran:

We, the Attorneys General of New York, Delaware, the District of Columbia, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, Oregon, and Vermont write today in opposition to the Proposed Rule "Establishment of Safeguards and Program Integrity Requirements for Health and Human Services-Funded Extramural Research Involving Human Fetal Tissue," 86 Fed. Reg. 2615 (January 13, 2021) ("proposed rule") and to urge the U.S. Department of Health and Human Services ("HHS") to withdraw it in its entirety.

The Biden administration has made clear through the January 27, 2021 Presidential Memorandum on restoring trust in government that heads of agencies should act in accordance with the six principles set forth in Section 1 of the Presidential Memorandum of March 9, 2009 regarding scientific integrity—including that each agency engage in "well-established scientific processes, including peer review where appropriate, and each agency should appropriately and accurately reflect that information in complying with relevant statutory standards."[1] Given that

[1] Presidential Memorandum, Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking, 86 Fed. Reg. 8845 (Jan. 27, 2021), available at https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/memorandum-on-restoring-trust-in-government-through-scientific-integrity-and-evidence-based-policymaking/.

the proposed rule fails to consider the importance of human fetal tissue ("HFT") in scientific research and medical advancements, and breaches fundamental concerns related to patient privacy, rejecting this proposed rule aligns with the Biden administration's policy of making "evidence-based decisions guided by the best available science and data."[2] Rejecting the proposed rule is also warranted because current rules and regulations already allow for safe HFT use and the security of personal information while supporting innovation in medical research.

The current public health crisis caused by the Coronavirus (COVID-19) demands that evidence-based decisions be among the nation's highest priorities, from ongoing treatments to vaccine development. HFT is a significant research tool for lifesaving biomedical research, and has led to the development of many vaccines, most recently in vaccines designed to combat COVID-19, among others. HFT use in research is beneficial because it can "produce cell cultures, also called cell lines, which can be maintained in a laboratory environment for very long periods of time, in some cases indefinitely . . . . Cultured cells mimic many of the properties that they have in a living body, and therefore can be used as a model for researchers studying basic biological processes."[3] HFT "grows readily and adapts to new environments, allowing researchers to study basic biology or use it as a tool in a way that can't be replicated with adult tissue."[4] Research demonstrates that HFT is also critical for understanding novel viruses and studying childhood cancers such as retinoblastoma, a cancer of the eye.[5]

HHS's current requirements for the procurement and donation of HFT provide appropriate safeguards for its use and allow for meaningful scientific contributions. The proposed rule offers no evidence that current rules and regulations do not work or undermine the ability of patients to provide informed consent. Instead, the proposed rule adds unnecessary and duplicative requirements, and in fact concedes that these changes are unwarranted as researchers are already required to obtain donors' informed consent. *See* 45 CFR §§ 46.116, 46.117. Rather than improve the exchange of healthcare data and consent to treatment among patients, providers, and researchers, or better streamline processes, the proposed rule increases the regulatory costs and administrative burdens.

I. The Proposed Rule Mandates Unnecessary and Duplicative Informed Consent and Enticement Requirements.

The proposed rule claims that the informed consent process of HFT procurement needs additional safeguards but fails to provide any supporting evidence indicating so. Current regulations have strong informed consent requirements. Federal law already requires written

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[2] *Id.*

[3] *See* Amanda MacMillan, *Fetal Tissue Research Facts and Why It's So Controversial*, (Feb. 2, 2021), available at https://www.health.com/mind-body/fetal-tissue-research-facts.

[4] *Id.*

[5] *See* Sally Temple & Lawrence S. B. Goldstein, *Why We Need Fetal Tissue Research*, Science Magazine (Jan. 18, 2019), available at https://science.sciencemag.org/content/363/6424/207.full.

informed consent from any donor of HFT. Sections 498A and 498B of the PHS Act (42 U.S.C. §§ 289g-1 and 289g-2) already set forth specific requirements and prohibitions on research involving HFT. Research involving HFT is also subject to the HHS Regulations for the Protection of Human Subjects. 45 C.F.R. §§ 46.204 and 46.206 are specifically relevant here. Additionally, existing regulations mandate general informed consent requirements, including consent requirements from a donor of tissue obtained pursuant to an induced abortion. *See* 45 C.F.R. §§ 46.116, 46.117, and 6 C.F.R. §§ 46.116, 46.117.[6] Further, many states require informed consent for the use of fetal tissue in research.[7] Similarly, Section 498B of the Public Health Service Act specifically prohibits any person from knowingly acquiring, receiving, or transferring any HFT for valuable consideration. Violation of this statute carries criminal penalties that apply to both those that supply and those that acquire HFT. States also have laws prohibiting enticements of HFT.[8]

Thus, the proposed rule's informed consent requirements add duplicative processes and unnecessary red tape to make it harder for patients to donate HFT and researchers to obtain HFT for scientific studies. The proposed rule's new requirements and consent forms are insensitive, inefficient, and irrational. For instance, the rule requires that a patient be issued consent forms at every turn—papering the patient at a potentially sensitive time—inducing confusion, which may leave patients with the impression that their medical provider should not be trusted or is biased against their decision to donate HFT. By contrast, there is no indication in any of the materials cited that the proposed rule specifically aims to address deficiencies in the current process. The proposed rule does not examine or offer relevant data, studies, or current or past violations of well-established consent requirements.

Therefore, the proposed rule does not add any meaningful requirements that would further a legitimate regulatory purpose, and, if anything, the requirements could harm patient-provider relationships.

II. The Proposed Rule Imposes Additional Administrative Costs and Creates Patient Confusion.

The proposed rule's unnecessary and duplicative requirements will impose significant administrative costs. New informed consent forms will need to be provided to and processed by an individual *other than* the individual who obtained the informed consent for the patient's abortion, effectively requiring additional staff at medical facilities to simply process consent forms. 86 Fed. Reg. at 2620-21. Requiring HFT donors to sign additional informed consents

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[6] *See also* 45 C.F.R. § 46.204 (2018) for requirements for research involving "pregnant women or fetuses," 45 C.F.R. § 46.205 (2018) for requirements for research involving neonates of uncertain viability and nonviable neonates.

[7] *See, e.g.*, 410 Ill. Comp. Stat. 110/15(c)(4, 5); Mich. Comp. Laws § 333.2688; N.J. Stat. Ann. § 26:2Z-2; NM Stat. Ann. 24-9A-5 (C) (2020).

[8] *See, e.g.*, 410 Ill. Comp. Stat. 110/45; N.J. Stat. Ann. § 26:2Z-2; NM. Stat. Ann. §24-9A-5 (B) (2020).

may undermine patient autonomy and their ability to provide informed consent if they are bombarded with forms by different parties. If a patient has a relationship with a medical professional, that person would normally be in the best position to have conversations regarding consent for new or additional procedures. Adding a new person for the sole purpose of obtaining informed consent for HFT donation could lead to confusion and distrust.

III. The Proposed Rule Mandates the Unnecessary Collection and Disclosure of Private Health Data of Patients Seeking Abortion Care.

The proposed rule requires the collection and distribution of private and protected healthcare data under the guise of "strengthen[ing] safeguards and program integrity." 86 Fed. Reg. at 2615. The proposed rule forces medical providers to give HHS full and unfettered access to "all informed consent forms obtained by the non-Federal entity[.]" While the proposed rule acknowledges that forms can be redacted "with respect to the name and signature of the [patient]" for privacy reasons, it nevertheless broadly grants HHS access to "all documents" and "all records" to prove that HFT was not transferred for valuable consideration and to confirm federal funds were not used to obtain the HFT from abortions. Without limitations, the disclosure of data could publicly identify patients who had abortions through identification of other information, including their treating doctors, medical care facility, and medical conditions.[9] In so doing, the proposed rule weakens privacy and security protections for sensitive health information and has the potential to compromise patient care by adding yet another layer of risk in disclosing patients' identities.

This broad-brush approach to data privacy is at odds with President Biden's January 27 Memorandum on restoring trust in government through scientific integrity and evidence-based policymaking, which seeks to balance scientific processes with appropriate protections for privacy.[10] Furthermore, the proposed rule's blanket requirement to provide all data from medical providers is in conflict with the major goal of the Health Insurance Portability and Accountability Act ("HIPAA")—to ensure that individuals' health information is properly protected while allowing the flow of information needed to promote high-quality healthcare. 86 Fed. Reg. at 2615, n.7.[11] Protecting the privacy of research participants has always been paramount in medical treatment and a fundamental tenet of clinical research—and nothing presented in the proposed rule indicates additional data access is necessary to determine whether federal funds were used to obtain HFT or whether monies were exchanged for fetal tissue donation.

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[9] The rule itself highlights this concern, acknowledging the "serious moral and ethical considerations involved in HFT donation" yet provides no limitations on how this information would be collected and used outside of the research context.

[10] Presidential Memorandum, Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking, *supra*, note 1.

[11] *Citing* Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research (Nass SJ, Levit LA, Gostin LO, eds., National Academies Press, 2009).

Ultimately, these professed "safeguards" to the disclosure of private data can undermine a patient's trust and willingness to donate fetal tissue for medical research.

IV. The Proposed Rule Unreasonably Limits Researchers' Access to Human Fetal Tissue.

The proposed rule would add a new paragraph to 45 C.F.R. § 46.206, mandating that research involving HFT from "elective abortions" be acquired *only* from a Federal or State Government, a Federal or State Government-owned entity, university, college, accredited degree-granting institution of higher education, university hospital, or academic medical center. 86 Fed. Reg. at 2633. This requirement seeks to prohibit researchers from acquiring HFT from organizations outside the scope of proposed paragraph (h), such as Planned Parenthood, which maintains programs that make fetal tissue available for the scientific community. The exclusion of organizations such as Planned Parenthood is incongruous with President Biden's January 27, 2021 Executive Order on the President's Council of Advisors on Science and Technology, directing agencies to "make evidence-based decisions guided by the best available science and data […] (and) seek from scientists, engineers, and other experts the best available scientific and technological information and advice."[12] Third-party institutions like Planned Parenthood have a history of compliance with applicable legal and medical standards, and there is no evidence-based justification for this exclusion.[13] Proposed paragraph (h) serves instead to unreasonably limit access to human fetal tissue research with no scientific justification for doing so.

The scientific community agrees that HFT research is integral in the advancement of healthcare research. For instance, cells from fetal tissue are used to evaluate conditions including Parkinson's disease, Amyotrophic Lateral Sclerosis ("ALS"), and spinal cord injuries.[14] Indeed, fetal tissue has been integral to the development of vaccines, from polio, rubella, and measles to the development of medical therapies against HIV/AIDS and, as discussed above, COVID-19.[15] Now is the time to align with scientists, clinicians, and medical

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[12] *President's Council of Advisors on Science and Technology*, Exec. Order 14,007, 86 Fed. Reg. 7615, § 1 (Jan. 27, 2021), available at https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/executive-order-on-presidents-council-of-advisors-on-science-and-technology/.

[13] Letter from Jim Esquea to Sens. Joni Ernst and Roy Blunt (Aug. 14, 2015), available at https://www.plannedparenthood.org/files/3514/4709/3497/HHS_Letter_2015_08_14_-_FT_Research.pdf.

[14] Shari E. Gelber, Laurence B. McCullough, and Frank A. Chervenak, "Fetal Tissue Research: An Ongoing Story of Professionally Responsible Success," American Journal of Obstetrics and Gynecology (Dec. 2015), pp. 819-821; Alan Trounson and Courtney McDonald, "Stem Cell Therapies in Clinical Trials: Progress and Challenges," Cell Stem Cell, vol. 17 (July 2, 2015), pp. 11-19.

[15] Gelber, et. al., *supra*, note 14; Shigeyoshi Fujiwara, "Humanized Mice: A Brief Overview on their Diverse Applications in Biomedical Research," Journal of Cellular Physiology, vol. 233

providers driven by a compounding public health crisis to improve on medical advances that ensure the well-being of all.

V. The 30-Day Comment Period Is Insufficient to Provide Meaningful Comment.

Finally, the undersigned Attorneys General express concerns with the timeline set by HHS for responding to the proposed rule. The notice of proposed rulemaking was published on January 13, 2021, and HHS imposed a deadline for comments of February 12, 2021, providing only a 30-day comment period. The Administrative Procedure Act ("APA") requires that agencies provide "interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments…." 5 U.S.C. § 553(c). The Executive Branch has interpreted this requirement to mean that a sixty-day comment period, at a minimum, is necessary to allow interested parties to have a meaningful opportunity to comment on proposed regulations.[16] The proposed rule deals with complex issues, and the Office of Management and Budget determined that the proposed rule is a "significant regulatory action." 86 Fed. Reg. at 2624. A comment period of only 30 days is insufficient for interested parties to provide meaningful comment on a significant proposed rule.

VI. Conclusion.

In light of the medical achievements made possible through HFT research and the potential for future scientific breakthroughs, we encourage HHS to focus on safe and effective measures that advance scientific research rather than endorse regulations that stall or slowdown that effort. The proposed rule imposes unnecessary, duplicative, and overly burdensome requirements on patients donating HFT when receiving abortion care, and the scientific community whose acquisition of HFT is critical for clinical studies. As stated above, the current rules and regulations in place offer safe, secure, and ethical procedures for patients to donate HFT and for medical researchers to obtain HFT.

The undersigned Attorneys General appreciate the Biden administration's commitment to public health, biomedical research, and evidence-based policies. We applaud the regulatory freeze memo calling for review of proposed rules like the instant one, and we urge you to

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(May 2017), pp. 2889-2901, and Kylie Su Mei Yong, Zhisheng Her, and Qingfeng Chen, "Humanized Mice as Unique Tools for Human-Specific Studies," Archivum Immunologiae et Therapiae Experimentalis, vol. 66 (2018), pp. 245–266; Akshay Syal, "How Cells Taken from Decades-old Fetal Tissue Are Used in Covid-19 Drug Research." (October 9, 2020), available at https://www.nbcnews.com/health/health-news/how-cells-taken-decades-old-fetal-tissue-are-used-covid-n1242740.

[16] *Regulatory Planning & Review*, Exec. Order 12,866, § 6(a)(1) (Sept. 30, 1993) (stating that, in most cases, a meaningful opportunity to comment on a proposed regulation should include a comment period of not less than 60 days); *Improving Regulation and Regulatory Review*, Exec. Order 13,563 (Jan. 18, 2011) (reiterating that an agency should generally provide the public with at least a 60-day comment period to allow the public to have a meaningful opportunity to comment on a proposed regulation).

withdraw it in its entirety. We look forward to working with this administration, and thank you for consideration of the above comments.

Sincerely,

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